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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,594	03/11/2004	Paul G. Alchas	P-5375	6362

7590 11/08/2005  
Becton, Dickinson and Company  
1 Becton Drive  
Franklin Lakes, NJ 07417

EXAMINER

WITCZAK, CATHERINE

ART UNIT PAPER NUMBER

3767

DATE MAILED: 11/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/798,594

Applicant(s)

ALCHAS, PAUL G.

Examiner

Catherine N. Witczak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/11/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Information Disclosure Statement*

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### *Specification*

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it is written in claim form. Correction is required. See MPEP § 608.01(b).

 11-2-05

### ***Drawings***

The drawings are objected to because numbers in the drawings do not correspond to the numbers in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Objections***

Claim 16 is objected to because of the following informalities: it is identical to claim 15. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

Claims 1-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Alchas et al, hereforth referred to as Alchas (US 2002/0068909).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention

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disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claims 1 and 14: Alchas discloses in Figure 8 a needle cannula having a needle tip (36) and a limiter (314 and 312). Alchas also discloses that the limiter is moveable from a first position (as shown in Figure 5) to a locked second position (as shown in Figure 8) in which the limiter is not movable (paragraph 50) and in which the needle tip (42) extends beyond the skin engaging surface (Figure 8, 318) a distance of 3mm or less (paragraph 45, lines 1-4). Furthermore, in respect to claim 14, Alchas also discloses in paragraph 42, lines 3-8 a container being adapted to contain a substance for intradermal injection that is in fluid communication with the needle cannula.

Claims 2, 3, 1, 16, and 17: Alchas discloses in paragraph 45, lines 1-4, a needle tip extending beyond the skin engaging surface in a range between 0.5mm and 3.0 mm.

Claims 4 and 18: Alchas discloses in Figure 8 a substantially planar skin-engaging surface (318).

Claims 5 and 19: Alchas discloses in Figure 8 a limiter (312 and 314) comprising: a support member arranged about the needle cannula (314) and an outer sheath (312) arranged about the support member which is selectively slidable from first to second positions.

Claims 6 and 20: Alchas discloses in Figure 8 a limiter (312 and 314) comprising a first means for releasably holding outer sheath in first position (322 and 320) and a second means for lockingly holding sheath in second position (328, 320, 324, and 326).

Claims 7 and 21: Alchas discloses in Figure 8 a retaining projection and stop member (322) on support member and a projection (320) on the sheath.

Claims 8 and 22: Alchas discloses in Figure 8 a proximal stop (328) arranged toward a proximal end of the support member (314) which prevents proximal movement of the inwardly directed projection from the retracted position.

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Claims 9 and 23: Alchas discloses in Figure 8 a recess formed between support member projections 326 and 328 that can accommodate the inwardly directed projection (320) of the sheath.

Claims 10 and 24: Alchas discloses in Figure 8 a distal stop (328) on the support member (314), a ramp (322), and an indent disposed therebetween, where the inwardly directed projection (320) when the limiter is in the extended position.

Claims 11 and 25: Alchas discloses in Figure 8 an inwardly directed projection (320) having a proximal edge, the ramp (322) having a distal edge, where the proximal edge of the projection is in abutting contact with the distal edge when in extended position.

Claims 12 and 26: Alchas discloses in paragraph 42, lines 3-8, a needle assembly comprising a hub around the needle cannula, with the hub adapted to accept a container for delivering a substance.

Claims 13 and 27: Alchas discloses in paragraph 48, lines 1-4 that the hub and support member (referred to as "limiter" in the reference) are unitarily formed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine N. Witczak whose telephone number is (571) 272-7179. The examiner can normally be reached on Monday through Friday, 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**KEVIN C. SIMMONS**  
**PRIMARY EXAMINER**

*Kevin C. Simmons*

*W*